

REMARKS

Applicant respectfully requests reconsideration. Claims 13, 17-22, 25-27 and 54-56 were previously pending in this application. Claim 14 has been canceled. Claims 17-19, 21, 25 and 54-56 have been amended to correct claim dependency in view of the cancellation of claim 14.

As a result, claims 13, 17-22, 25-27 and 54-56 are pending for examination. No new matter has been added.

Applicant appreciates the courtesy extended by the Examiner and her supervisor in granting an interview on April 24, 2008.

Priority

The Examiner alleged that the disclosure of the parent application (serial number 09/347,311) of Applicant's present application does not support the present claims. Of particular note, the Examiner stated that "the disclosure of 09/347,311 is completely silent about the claimed methods and method steps." Office Action at page 3. Applicant respectfully disagrees with the Examiner's characterization of the support in the '311 parent application, and provides below a description of the support for the claims as pending.

First, Applicant submits that original claim 73 of US 09/347,311 as dependent from claims 60-67, particularly claims 60 and 61, supports the subject matter of present claim 13. In addition, claim 76, specifically recites that the organism fed with the microorganism is *C. elegans*. These claims are reproduced below for the convenience of the Examiner.

73. A method for introducing dsRNA or DNA capable of producing dsRNA into an organism, which method comprises feeding said organism with a suitable microorganism comprising an expression vector according to any of claims 60 to 67 or feeding said organism directly with an expression vector according to any of claims 60 to 67.

60. An expression vector for use in a method according to any proceeding claim comprising a promoter or promoters oriented relative to a DNA sequence such that they are capable of initiating transcription of said DNA sequence to double stranded RNA upon binding of an appropriate transcription factor to said promoter or promoters.

61. An expression vector according to claim 60 comprising two identical promoters flanking the DNA sequence.

76. A method according to any of claims 73 to 75 wherein said organism is *C. elegans* and said microorganism is *E. coli*.

Second, additional support clearly is found in the specification as filed. Examples of this support are found at page 16, line 2 to page 18, line 28 (particularly at page 17, lines 17-28); page 19, line 35 to page 21, line 4; and page 28, lines 12-34. Additional support is described below in connection with the rejection under 35 U.S.C. 102.

Based on the foregoing description of the support for the presently claimed invention in the '311 parent application, Applicant respectfully requests that the Examiner withdraw the objection to the priority claim.

Claim Objections

The Examiner objected to claim 14 as a substantial duplicate of claim 13. Applicant has canceled claim 14, rendering the objection moot.

Rejection Under 35 U.S.C. § 102

The Examiner rejected claims 13-14, 17-22, 25-26 and 54-56 under 35 U.S.C. §§ 102(b) and 102(a) as being anticipated by Fire et al. (WO99/32619, the "Fire PCT application") and under 35 U.S.C. 102(e) as being anticipated by Fire et al. (U.S. 6,506,559 B1, the "Fire patent"). Applicant respectfully traverses the rejection and requests reconsideration.

The effective filing dates of the Fire PCT application and the Fire patent do not extend to the earliest filing date, i.e., the US provisional application 60/068562 (the "Fire provisional") for at least the following reasons. The Fire provisional does not disclose feeding *C. elegans* with a microorganism that expresses dsRNA corresponding to a gene of interest. The Fire provisional also does not disclose that the microorganism comprises an expression vector that comprises a DNA sequence corresponding to the gene of interest. Further, the Fire provisional does not teach that this expression vector comprises a promoter or promoters flanking said DNA sequence such that the promoter or promoters initiate transcription of said DNA sequence to produce double stranded RNA upon binding of a transcription factor to said promoter or promoters.

The Fire provisional discloses that dsRNA can be synthesized *in vitro* or *in vivo* (see, e.g., page 7, lines 11-15; page 11, lines 17-24; page 15, line 5). The dsRNA that is produced is introduced into cells or organisms primarily by injection (see throughout the application, e.g., at page 7, lines 16-19; figure legends to Figs. 2-4 at pages 8-10; page 12, lines 1-12; page 16, lines 18-23; Table 1). The Fire provisional discloses that strands can be purified and annealed prior to injection (see, e.g., page 11, lines 23-29; page 15, lines 16-26, page 17, lines 23-26).

Clearly, the Fire provisional does not disclose each and every element of the claimed invention, and therefore does not provide priority for the aspects of the cited Fire PCT application or the Fire patent that relate to Applicant's claimed invention.

Applicant's priority documents support the claimed invention. Applicant's first priority application, GB 9814536.0, was filed on July 3, 1998, well prior to the publication of the Fire PCT application. Applicant's second priority application, GB 9827152.1, was filed on December 9, 1998. This date also is prior to the publication of the Fire PCT application.

Exemplary support for the claimed invention is found in the first priority filing, at least as follows:

Aspects relating to feeding bacteria: page 1, lines 16-22; page 2, lines 27-30; page 9, line 12 to page 10, line 6; page 11, lines 30-33; page 13, line 6-23; page 14, lines 22-23; page 14,

lines 31-33; page 14, lines 19-23; page 14, lines 31-33; page 15, lines 14-17; page 15, lines 21-26; page 16, lines 5-14; page 17, lines 3-5; page 17, line 32 to page 18, line 1; page 19, lines 10-15; claims 1-15.

Aspects relating to making dsRNA by vector, in micro-organisms: page 2, lines 19-27; page 3, lines 16-19; page 4, line 26 to page 5, line 3; page 6, lines 19-22; page 7, line 25 to page 8, line 16; page 10, line 28-35; page 14, lines 10-22; page 15, lines 9-14 and 21-25; page 17, lines 26-28; claims 1-19; Figure 3, Figure 4, Figure 6, Figure 7 and descriptions thereof.

Exemplary support for the invention is found in the second priority filing, at least as follows:

Aspects relating to feeding bacteria: page 3, lines 1-9; page 13, lines 25-30; page 14, line 25 to page 15, line 1; page 15, lines 18-20 and 22-30; page 16, lines 3-5; page 16, line 31 to page 17, line 25; page 19, lines 5-8; page 19, line 32 to page 11; page 20, lines 22-30; page 20, line 34 to page 21, line 4; page 21, lines 17-20; page 22, lines 15-21; page 23, lines 7-12; page 24, lines 23-29 and 32-33; page 25, lines 8-10; claims 8-10 and 50-55; Figure 3.

Aspects relating to making dsRNA by vector, in micro-organisms: page 1, line 30 to page 3, line 9; page 4, lines 5-22; page 5, line 29 to page 6, line 17; page 8, line 22 to page 9, line 8; page 10, lines 1-28; page 11, line 14 to page 12, line 6; page 12, line 8 to page 13, line 30; page 14, lines 17-30; page 16, line 13 to page 17, line 13; page 17, lines 15-19; page 19, line 14 to page 20, line 1; page 20, lines 14-27; page 20, line 34 to page 21, line 3; page 23, lines 2-4; claims 1-28 and 50-55; Figure 3, Figure 4, Figure 6, Figure 7 and descriptions thereof.

Therefore, both of the priority applications for the instant application clearly support the invention now claimed. In contrast, the Fire provisional application does not support any such invention.

As a result, neither the Fire PCT application nor the Fire patent anticipates the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 13, 17-22, 25-26 and 54-56 under 35 U.S.C. §§ 102(a), 102(b) and 102(c).

Rejection Under 35 U.S.C. § 103

The Examiner rejected claims 13-14, 17-22, 25-27 and 54-56 under 35 U.S.C. 103(a) as unpatentable over Fire et al. (WO 99/32619 A1, the “Fire PCT application”) or Fire et al. (U.S. 6,506,559 B1, the “Fire patent”) as applied to claims 30-39, 70-74 and 80-83 (*sic*) further in view of Talkad et al. (J. Bacteriol. 135: 528-541, 1978). Applicant respectfully traverses the rejections and requests reconsideration. For the purposes of the response, Applicant assumes that the reference to claims 30-39, 70-74 and 80-83 was a typographical error and that the Examiner meant to reference the claims rejected under 35 U.S.C. 102, i.e., claims 13-14, 17-22, 25-26 and 54-56.

The deficiencies in the disclosure of the Fire provisional application, which serves as the priority document for the Fire PCT application and the Fire patent, respecting the claimed invention are discussed in the response to the anticipation rejection above.

In contrast, as demonstrated above, both of the priority applications for the instant application clearly support the invention now claimed.

According to the Examiner, the Talkad et al. reference describes *E. coli* strains deficient in RNase III and that RNase III cleaves bacteriophage T7 RNAs as well as double-stranded RNAs. According to the Examiner, it would have been obvious to substitute the *E. coli* strains deficient in RNase III of Talkad et al. for the strains used in the Fire PCT application and the Fire patent.

Applicant's response is that even if such a substitution was made, the Talkad et al. reference does not supply any other of the elements of the claimed invention that are missing from the Fire PCT application and the Fire patent.

As a result, neither of the combinations of references provide all of the elements of the claimed invention and thus neither of the combinations of references render the claimed invention obvious.

Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 30-40, 70-74 and 80-83 under 35 U.S.C. § 103(a)

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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Docket No. D0590.70011US00
Dated: June 16, 2008
X06/14/08x